Predictors of outcome in patients with common mental disorders receiving a brief psychological treatment: an exploratory analysis of a randomized controlled trial from Goa, India

V Patel[1,2], H Weiss[1], A Mann[3]
[1]Department of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, London, England
[2]Sangath Society, Goa, India
[3]Section of Epidemiology, Institute of Psychiatry, London, England

Abstract
Objective: A randomized placebo-controlled trial of treatment for common mental disorders in Goa, India found that psychological treatment (problem-solving) was no more effective than placebo. The study aimed to identify factors predicting outcome amongst participants receiving the psychological treatment, as measured by score on the Revised Clinical Interview Schedule (CISR). **Method:** The CISR scores at 2 months, 6 months and 12 months were modelled using multiple linear regression with a random effect for patients. Two types of variables were examined. Patient variables were age; sex; religion; education; marital status; severity of psychiatric morbidity at recruitment; and severity of social and life problems faced by the subject. Treatment variables were number of sessions attended and the hospital site. **Results:** About half the participants had a depressive disorder; most of the remainder had mixed anxiety-depression. Overall adherence with the intervention was low; more than a third of patients attended only one session. Attending a greater number of sessions and facing a severe life problem were significantly associated with a worse outcome ($p<0.005$). **Conclusion:** The severe nature of life problems faced by some patients with common mental disorders may limit the efficacy of clinic-based psychological treatments in low income countries.

Key words: Outcome assessment; Mental disorders; Psychological techniques; India

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Introduction

The authors have published the findings of a randomized controlled trial comparing the efficacy and cost-effectiveness of antidepressant and a psychological treatment with placebo for Common Mental Disorders (CMD) in general health care settings in Goa, India.[1] This trial, which was the first of its kind from a developing country, reported that antidepressants were significantly superior on clinical and economic outcomes as compared to placebo, particularly in the short-term. However, the psychological treatment (problem-solving) was not superior to placebo on any of the outcomes at any point of follow-up over one year. The lack of efficacy of the psychological treatment was surprising given that the authors had anticipated that the opportunity to discuss emotional symptoms would have had some therapeutic benefit in the setting of a busy, public hospital out-patient clinic where the average consultation time was less than 5 minutes. The treatment was derived from treatment protocols which had been used in previously successful trials in the UK.[2] The

Correspondence
Prof Vikram Patel
Sangath Centre, 841/1 Alto Porvorim, Goa 403521, India
email: vikram.patel@lshtm.ac.uk

treatment had been adapted for use in the Indian setting, reviewed by experts in the country and piloted in the same study settings.[3]

The recent Lancet series on global mental health calls for action to scale up evidence based services for people with mental disorders, particularly in low income countries where the treatment gaps are the largest.[4] Questions remain, however, about the generalisability of evidence from well-resourced settings, in particular related to psychological treatments, to low-income settings where social services and skills for psychological treatment are scarce and cultural explanations of mental illness may not be consonant with psychological theories developed in the West.[5] This paper presents further analyses of the trial in India, restricted to the psychological treatment arm of the trial.[1]

The aim is to study the role of a number of variables in determining factors associated with a poorer outcome amongst participants receiving psychological treatment. The variables which we hypothesized were grouped in two categories, patient factors and treatment factors. Patient factors were: age of the subject; sex; religion; education; severity of psychiatric morbidity; and nature of social and life problems faced by patient. Treatment factors were number of sessions attended; and hospital site.

Method

Sample

Details of the methodology of the trial are described elsewhere.[1] The study population was made up of attenders at the general medical out-patient clinic of the two main district general hospitals in Goa, a state in west India. Only subjects who gave informed consent (written for literate subjects) were enrolled. Three treatment arms were defined: antidepressant (fluoxetine), placebo and the psychological treatment. Power calculations were used to determine the sample size required to demonstrate a clinically significant change in the score of the psychiatric outcome was 150 subjects in each arm of the trial. Consecutive patients aged 17 and above who satisfied inclusion criteria were screened using the 5-item version of the General Health Questionnaire (GHQ). The GHQ is a screening measure for the detection of CMD; the translation and validation of the short version of the GHQ in the Konkani language has been published.[6] Those who scored 4 or more were interviewed with the Revised Clinical Interview Schedule (CISR), which is a standardised, structured interview for the measurement and diagnosis of CMD in community and general health care settings.[7] Subjects who scored 15 or more were invited to enter the study. The randomization list was drawn up by the first author using random number tables, in blocks of 9 subjects. Consecutive subjects, upon enrolment, were given a patient number, based on the next available number in the study register. Subjects who were assigned to psychological treatment were given instructions to see the therapist, who was located in an office in the hospital. From this point onwards, psychological treatment subjects had no further contact with the research team, except for review assessments. There was no attempt for masking in the case of subjects allocated to the psychological treatment arm. Ratings of outcomes (CISR) at 2, 6 and 12 months were made by field researchers who had no contact with the therapists.

Psychological treatment

The salient components of the psychological intervention were:

1. Explanation of the nature of the treatment and why the patient is being given the treatment, and establishment of rapport
2. Explanation about the aetiology of the symptoms and the diagnosis
3. Relaxation [Breathing Exercises] to manage anxiety symptoms
4. Treatment for Specific Symptoms such as panic attacks, sleep problems or tiredness, as reported by the subject (during the CISR interview)
5. Problem-Solving: In addition to the well defined steps for problem-solving treatment[8], specific suggestions for common problems, such as violence in the family and relationship problems, were provided in a directive fashion, in keeping with the findings of the pilot study which suggested that such an approach was more acceptable to patients in this setting.
6. Referral to appropriate helping agencies whenever possible. Details of the development and piloting of the therapy procedure is published elsewhere.[3]

Each therapist was based in a specific hospital; thus a particular subject saw the same therapist at each session. The therapist made appointments directly with the subject, usually at weekly intervals for the initial sessions and fortnightly thereafter up to 6 to 8 sessions; additional sessions could be provided if the therapist felt these were necessary. The problem-solving component was initiated usually in the second session. The course of therapy was scheduled to last up to 3 months after recruitment. If a subject did not come for an appointment, the therapist sent a reminder letter. All subjects were free to consult any doctor they wished during the study period and were free to leave the study at any time. No restrictions were placed on the use of medications prescribed by the subject's regular physician.

Analyses

All the hypothesized predictors were measured at recruitment of the subjects, with the exception of the rating of the severity of the life problem faced by subjects. The problems faced by individual subjects were rated using a dichotomous scale:

1. Severe life problems which were beyond the control of the subject ('Severe'). The most common types of problems rated as 'severe' were those related to other family members or when other family members were unwilling to help the patient; severe economic problems and isolation in older subjects. Examples of common problems which were rated as severe are given in the appendix.
2. Mild problems included those which did not fit in the severe category and included problems which were the result of the subject's mental illness, which were felt to be soluble by feasible actions taken by the subject, or when the subject had adequate social support. Thus, examples of 'mild' problems included patients with panic attacks but no major life difficulties, patients who had lost social contact with friends because of the somatic symptoms and loss of interest associated with their depression, and patients whose spouses or other family members were

supportive and would, when invited, attend therapy sessions.

The problems were rated by two raters. The first rating was made by the treating therapist, on the basis of the first or second interview with the subject. Thus, the first rating was made blind to the outcome measurements of the subject's mental health. Detailed notes were made of the problems faced by the subject. The second rating was made by the other therapist, blind to the treating therapist rating and subject outcomes, based on the case notes of the nature of the problems prepared by the treating therapist. The two sets of ratings were identical for two-thirds of subjects. For the remainder, a third rater (VP) rated the case notes; this rater was not blind to the ratings made by the two therapists, but was blind to the outcome for the subject. The rating by the third rater was considered be the final rating, since it would represent the 'best of three' ratings.

All participants randomised to the psychological treatment arm who included at least one outcome assessment were included. The CISR scores at 2 months, 6 months and 12 months were modelled by use of linear regression with a random effect for patients. The models included the baseline measure to control for pre-treatment CISR score and time (since the 2-month assessment). Variables significantly associated with differences in CISR score in this initial analysis were included in a multivariate analysis.

Results

Sample

A total of 150 subjects were randomized to the psychological treatment arm. Data on all predictor variables collected at recruitment were available on all 150 subjects. Only about half the participants had a 'pure' depressive disorder (n=78); the rest had either a mixed anxiety-depressive disorder (n=63) or a 'pure' anxiety disorder (n=9).

Ratings of the severity of life problems were only available for 129 subjects. The case note material for the remaining 21 subjects was not adequate to obtain a reliable rating of the life problems faced. Of the remaining 129 subjects, more than half (n=75, 58%) were rated to suffer from a 'mild' problem while the remainder (n=54, 42%) were rated to suffer from a 'severe' problem.

Adherence with the psychological treatment was poor; 38% attended only one session, and only 10% attended 5 or more sessions. Overall, the mean number of sessions attended were 2.4 (sd 1.5).

The mean CISR scores at recruitment for the sample, according to various predictor variables are shown in Table I. CISR scores over the follow-up period were significantly higher in older persons, and those who had severe life problems.

Predictors of outcomes

In univariate analyses, there was a significant association ($p<0.05$) of older age, attending more than one session of

Table I: Mean CISR score by socio-demographic and behavioural characteristics

Variable	*Mean CISR score (S.D)*				
	N 1	*Baseline*	*2 months follow-up*	*6 months follow-up*	*1 year follow-up*
Age					
<40	36	25.7 (6.5)	11.5 (10.7)	13.5 (11.3)	14.5 (12.1)
40-49	32	22.1 (5.5)	12.5 (11.8)	11.0 (9.6)	10.5 (9.7)
50-59	45	23.7 (5.4)	13.8 (10.2)	12.7 (11.1)	13.8 (9.2)
≥60	37	24.1 (5.5)	14.7 (11.1)	18.9 (9.9)	18.0 (10.5)
Gender					
Female	122	24.3 (5.8)	14.0 (10.8)	14.2 (10.9)	14.8 (11.0)
Male	28	22.2 (5.5)	9.2 (9.9)	13.9 (10.4)	13.2 (8.1)
Marital status					
Married	97	23.3 (5.6)	13.2 (10.7)	14.1 (10.6)	14.4 (10.3)
Single/div/wid	53	25.0 (6.0)	13.3 (11.1)	14.3 (11.3)	14.7 (11.0)
Religion					
Hindu	72	24.5 (5.7)	12.9 (10.7)	14.5 (10.0)	14.5 (9.6)
Other	78	23.4 (5.9)	13.5 (11.0)	13.8 (11.5)	14.5 (11.3)
Education					
<1 year	91	23.5 (5.7)	13.1 (10.8)	14.8 (11.3)	15.5 (10.7)
1-4 years	23	23.4 (4.8)	13.7 (10.9)	11.9 (10.5)	11.4 (9.9)
≥5 years	36	25.3 (6.5)	13.4 (11.0)	13.9 (9.7)	14.2 (10.2)
No. sessions					
1	57	24.2 (6.2)	11.4 (9.9)	11.7 (10.1)	12.5 (9.6)
>=2	92	23.7 (5.6)	14.2 (11.2)	15.3 (11.1)	15.6 (10.8)
Life problems					
Mild	75	23.2 (5.5)	11.3 (9.7)	12.2 (9.9)	12.0 (9.5)
Severe	54	24.7 (6.7)	17.0 (11.7)	18.3 (11.1)	18.7 (10.0)
Hospital					
Asilo	75	25.0 (5.9)	13.5 (10.6)	14.9 (10.3)	14.1 (9.9)
Hospicio	75	22.8 (5.6)	13.0 (11.0)	13.5 (11.3)	14.9 (11.1)

Table II: Univariate mixed model analyses of repeated CISR scores from 2 to 12 months (adjusted for CISR at baseline and time)				
	Coefficient	*S.E.*	*p-value*	*95% CI*
Age				
<40	0			
40-49	-0.008	2.49	1.00	-4.9-4.9
50-59	1.05	2.21	0.64	-3.3-5.4
≥60	4.60	2.29	0.045	0.1-9.1
			p for trend=0.04	
Gender				
Female	0			
Male	-1.49	2.13	0.48	-5.7-2.7
Marital status				
Married	0			
Single/div/widowed	-0.71	1.70	0.68	-4.0-2.6
Religion				
Hindu	0			
Other	0.32	1.63	0.84	-2.9-3.5
Education				
<1 year	0			
1-4 years	-1.47	2.22	0.51	-5.8-2.9
≥5 years	-1.68	2.01	0.40	-5.6-2.3
No. of sessions				
1	0			
>=2	3.47	1.68	0.04	0.2-6.8
Type of problem				
Mild	0			
Severe	5.28	1.66	0.001	2.0-8.5
Hospital				
Asilo	0			
Hospicio	0.74	1.64	0.65	-2.5-4.0

treatment, and with the life problem being rated as being severe, with poor outcome. Marital status, gender, religion, education and hospital site were not associated with the outcome (Table II).

On multivariate analyses, attending more than one session and severe life problems were strongly associated with a poor outcome (p<0.005). There was borderline evidence of worse outcome with older age (p-value for trend=0.07) (Table III).

Discussion

A randomized controlled trial of psychological and antidepressant treatment of common mental disorders in general health care by the authors showed no benefit of a psychological treatment on any of the outcomes (psychiatric morbidity, disability and cost-effectiveness) when compared to placebo.[1] The lack of efficacy was disappointing given the fact that the psychological treatment had been piloted locally and both therapists had considerable experience[3], and that we had anticipated that, at the very least, the access to a therapist to talk about one's health and problems might be beneficial. This paper describes an exploratory analysis of the data aiming to investigate the predictors of outcome amongst participants randomly allocated to the psychological treatment. The finding

Table III: Multivariate mixed model analyses of repeated CISR scores from 2 to 12 months				
	Coefficient	*S.E.*	*p-value*	*95% CI*
Age				
<40	0			
40-49	3.26	2.50	0.19	-1.7-8.2
50-59	2.35	2.12	0.27	-1.8-6.5
≥60	4.56	2.29	0.05	0.1-9.1
			p-trend=0.07	
No. of sessions				
1	0			
>=2	4.92	1.74	0.005	1.5-8.3
Type of problem				
Mild	0			
Severe	5.62	1.68	0.001	2.3-8.9

of these analyses suggest that overall adherence with the intervention was poor. Two variables independently predicted a poor outcome, viz., severe life problems and attending more than one session of the treatment.

This analyses shows two distinct groups of subjects who fared poorly in the psychological treatment arm. First, were those subjects with severe life problems (see Appendix for examples). The types of problems which were rated as 'severe' were those which were typically beyond the control of the subject and most often consisted of severe economic problems and family dysfunction. Thus, the lack of efficacy of the psychological treatment for common mental disorders in this study setting may be, at least in part, because a significant number of subjects were facing severe social and economic problems for which a clinic-based psychological treatment was not effective.

Another reason we expected to explain the lack of effectiveness of the psychological treatment was the low adherence to the recommended treatment protocol; thus, the average number of sessions attended was only between 2 to 3 (a third of subjects attended only one session). However, to our surprise, subjects who attended more than one session also had a trend for worse psychiatric morbidity at follow up. This finding is counter-intuitive for it suggests that attending more sessions is associated with a worse outcome, even after adjustment for confounders such as clinical severity and life problems. We speculate that this finding is related to the fact that whereas some subjects who felt much improved after one session ceased to attend more sessions, others whose illness remained severe or worsened after recruitment, attended more than one session and had poor outcomes.

Our other hypotheses, principally that low education would predict a poor response, were not found to be correct. There was no variation in outcome between the two hospitals, between men and women, and on the basis of religion. Older subjects showed a poorer response, perhaps reflecting the lack of acceptability of talking treatments in this age group and the co-morbidity with physical health problems.

Since the publication of the trial from which these data were analysed, a number of new trials have confirmed the efficacy of interpersonal therapy or cognitive behaviour therapy delivered in community settings[9,10] or cognitive therapy based interventions delivered as part of a complex stepped care intervention in primary care facilities where antidepressants are also available.[11] The question remains why problem-solving, a relatively simple behavioural intervention, did not work in our trial, in spite of robust evidence of its efficacy in developed countries. Two reasons which are obviously evident are the low adherence levels with the treatment (which, however, questions its acceptability) and that the chosen intervention (problem solving) has only been previously found to be effective for the narrow diagnostic category of depression (whereas half of our sample also had significant anxiety symptoms).

We suggest also that a purely clinic based problem-solving intervention may not always be appropriate in resource poor settings. This treatment, when used in developed countries, relies on two major allies in the social sector: first, support for material difficulties is available in most developed countries built on the principle of a welfare state. Unemployed persons, for example, may access unemployment benefits and register with job centres. In India, there are no benefits, and most persons work in the informal sector where there is virtually no employment security. The second key ally is the extensive and highly-skilled social and family welfare system which helps individuals deal with social problems such as violence. Such a system is virtually absent in many low income countries. In such a setting, the solutions to problems are almost unattainable for the most severe economic and social difficulties and virtually beyond the scope of a clinic based intervention.

We note that other trials which have demonstrated the efficacy of psychological treatments have either used a group therapy approach, located their intervention in a community (as opposed to facility) setting, or combined the psychological treatment as part of a package including antidepressants. Thus, context is potentially a critical factor which interacts with the efficacy of psychological treatments. Group interventions are commonly used as a means to overcome severe socio-economic difficulties, for example, through microcredit schemes; this may partly explain the greater effectiveness of these approaches. It is possible, then, that individual facility based treatments may be a less effective approach to deliver psychological treatments in settings with scarce social welfare nets.

We acknowledge a limitation of this secondary analysis of the trial data, notably that we cannot be assured that ratings of the life problems were made blind to the severity of the ultimate outcome (since ratings were made at the end of the trial). The agreement of the rating of severity was relatively low although this is perhaps not surprising since one therapist rating was based on only the case notes, while the other had both the case notes and the face-to-face session contact. However, it is clear that the ratings were not dependent on the initial severity of psychiatric disorder which was similar in subjects with severe and mild life problems. If we had considered the analyses described in this paper as a primary hypotheses, we would have included an independent rating of life problems at the time of recruitment of subjects so that the rating was genuinely independent from therapist experiences. We would also have been able to compare the interaction of life problem severity with the effect of other drug interventions. Indeed, as with most post-hoc secondary analyses, our analyses were not guided by an a priori conceptual or theoretical framework and factors which may have been important predictors of outcome were not assessed.

We also acknowledge that the small number of therapists limits our ability to infer whether inter-therapist variance influenced outcomes. We also did not have data on the fidelity of the intervention which may influence outcomes; thus, it is possible that our study findings might not generalise to problem-solving as a theoretical model.

Future trials should incorporate a measure of the nature of a person's life difficulties and problems as one of the explanatory variables which may influence the outcome of interventions for common mental disorders. A system of evaluation of life difficulties such as that developed by

Brown and colleagues[12] which classifies life events into categories such as humiliation and entrapment may be a useful strategy.

Conclusion

The findings reported in this paper should be considered as exploratory and suggestive that the efficacy of psychological treatments across health systems may be influenced by health system factors such as the severity of economic hardships, setting and form of the intervention delivery and the availability of social welfare systems. Based on our findings and those of other trials cited, more sophisticated psychological treatments adapted for use by non-specialist health workers, delivered in community or group formats, or integrated with a complex package of care including antidepressants, are the most promising method of treatment for common mental disorders in low resource settings.

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Appendix

Case Examples of Severe Problems

T is a 65 year old woman who has a teenage son and daughter. Her family makes mud pots and sells them in the market. Her son was a driver but had lost his job and is currently unemployed. Her husband is old and visually handicapped. The income that they received from selling mud pots was insufficient for the family. T listened to the explanation by the therapist in the first session and then asked: ''can you find my son a steady job? If he gets a job I will surely be fine''

P is a frail 78 year old woman who lives with her infirm husband who is bed-ridden and needs constant care and attention. They were a childless couple and her only close relative, a nephew who used to visit them occasionally, had died in a tragic accident in the previous year. Her main problems were related to her husband's sickness, her isolated lifestyle, her own deteriorating physical health and the lack of social support in the community.

E is a 36 year old malnourished single mother who is the sole carer for 2 school going children. She worked in a factory where she earned a daily wage of Rs 30/- per day and since she was sick she had to remain absent from work as a result they had no money to buy food. In her first counseling session she said ' I don't have the money to buy myself medicines that the doctor has prescribed and until I get alright I cannot go back to work which means my children will have to go hungry. Tell me what can I do?''